Examining Perceptions of Participation in a Pediatric IBD Collaborative: Analyzing the Sustainability of Quality Improvement Activities

By

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Abstract

In 2007, pediatric gastroenterologists from ten practice sites across the U.S. created a quality improvement collaborative, now known as ImproveCareNow, to improve the quality of care provided to children with inflammatory bowel disease. Despite the face validity and great potential of quality improvement collaboratives, investigators do not fully understand how improvement happens, including the variables contributing to quality measures and the necessary components needed to sustain quality improvement. The purpose of this project was to explore perceptions of collaborative participants to identify elements of sustainability.

We performed qualitative interviews with 16 ImproveCareNow participants as one method in a triangulated strategy of measuring collaborative participants' perceptions. We selected informants from a diverse list of practice types and geographic locations, and asked open-ended questions, which we then transcribed and coded. For this master's paper's focus on sustainability, I extracted participant views of the collaborative's most valuable aspects, obstacles to participation, and perceptions of variables affecting outcome measures.

New site participants found practice standardization to be most valuable; existing sites named a patient tracking, collaboration, and quality improvement training. New and existing sites mentioned time as the biggest obstacle to collaborative participation; existing sites, with more experience, also named persuading non-ICN providers to support the effort, and other challenges varied by particular ICN activities. Finally, 9 of 12 (75%) informants said that collaborative activities were responsible for improved inactive disease rates, and 3 of 12 (25%) said the ICN collaborative was partially responsible. When asked if other factors were affecting outcomes, 4 of 12 (33%) said no; 2 of 12 (17%) said yes; and 6 of 12 (50%) were uncertain.

Analyzing in-depth interviews of ICN participants is the first step in understanding what health care providers perceive as the value from, benefits of, and challenges to initiating and sustaining collaborative quality improvement activities.

Perspective/Author's Note

This master's paper represents just a portion of a larger team project that allowed my friend and colleague Thomas Runge and me to employ qualitative research tools to examine this pediatric IBD collaborative. Working together, we were able to examine the perspectives of collaborative participants and explore the literature on quality improvement collaboratives in greater depth than either one of us alone could have achieved. Therefore, the work completed for the master's paper and practicum requirements was a collaborative effort, in which we both contributed equally at every stage.

Although our master's project examined the perceptions of participation in a pediatric IBD collaborative, I chose to focus on elements of sustainability of particular ICN activities and the Improve Care Now (ICN) collaborative itself, while Thomas chose to focus on the practice variation and implementation of key ICN activities. We hope to present our combined work, including findings not fully represented in our master's papers, to the ICN Research Committee and we intend to publish our combined results in a peer-reviewed journal. Overall, sustaining quality improvement requires systems change and commitment at every level of the health care system.

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This project would have been possible without the guidance, expertise, and support from my two advisors and readers, Dr. Sue Tolleson-Rinehart and Dr. Mike Kappelman. I would also like to extend my gratitude to my friend and colleague in this project, Thomas Runge. In addition, I would like to thank Dr. Anna Schneck, Director of the Public Health Leadership Department, for providing Thomas and me with travel grants so that we could observe and present our work at an ImproveCareNow learning session. Finally, I am appreciative of the ImproveCareNow collaborative members who were very cooperative in their responses and generous with their time.

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Introduction

Pediatric inflammatory bowel disease (IBD) represents one of several chronic diseases that are the focus of quality improvement efforts in the U.S. Chronic diseases are the leading causes of death and disability in the U.S.,[1] making their management an important focus of quality improvement and prompting the development and utilization of the chronic care model, improvement collaboratives, health information technology, pay for performance financial incentives, and report cards.[2] Recognizing that addressing practice variation is an important step in quality improvement, a group of pediatric gastroenterologists from ten centers across the country formed the first pediatric IBD quality improvement collaborative in 2007,[3] now known as ImproveCareNow. Since then, the collaborative has grown to represent 23 sites. As of 2009, more than 2,500 patients have been enrolled in a pediatric IBD registry, and data from over 7,500 visits have been collected and analyzed.[4] Preliminary data indicate a rise in the rate of disease inactivity from 49% at the beginning of the collaborative to 64% in 2009. Can collaborative activities be said to account for any of the improvement in inactive disease? Identifying the drivers of outcomes improvement within and outside the collaborative is necessary to understanding how quality improvement occurs.

Assuring health care quality in the U.S. began more than a century ago when Ernest Codman convinced the founders of the American College of Surgeons to adopt a system of measuring patient outcomes.[5] By the 1960's, assessing quality expanded beyond patient outcomes. Avedis Donabedian outlined a framework for quality measurement, consisting of three components – structures, processes, and outcomes.[6] *Structural measures* are characteristics of the setting in which care is delivered. *Process measures* represent the steps health care providers take in the care of a patient. *Outcome measures* indicate changes that occur in a patient's health status as a result of a health care intervention.

John Wennberg and Alan Gittelsohn revived the quality of care conversation two decades later by introducing the concept of practice variation, after they demonstrated the existence of small area practice variations in the utilization of health services and their associated costs.[7] Unwarranted variation in care may be associated with misuse, underuse, and overuse of health care resources and services.[8, 9] Performance variation, a type of unwarranted variation, is the difference between optimal performance and observed practice.[10, 11] Quality improvement science involves addressing such variation, using methods adapted from other industries. For instance, the Institute for Healthcare Improvement based its Model for Improvement in large part on W. Edwards Deming's approach to management, the System of Profound Knowledge.[12]

Quality improvement finally came to public attention when the Institute of Medicine (IOM) found that serious and widespread quality problems existed throughout American medicine.[8] and subsequently released its reports *To Err is Human* in 2000[13] and *Crossing the Quality Chasm* in 2001.[14] The IOM defined *quality of care* as "the degree to which health services for individuals and population increase the likelihood of desired health outcomes and are consistent with current professional knowledge."[15] In *To Err is Human,* the IOM reported that "tens of thousands of Americans die each year from errors in their care, and hundreds of thousands suffer or barely escape non-fatal injuries."[13] *Crossing the Quality Chasm* concluded that "between the health care we have and the health care we *could have* lies not just a gap, but a chasm."[14] Reviving Codman's sense of accountability among clinicians, the IOM reports emphasized systemic changes in the health care delivery system to improve health care quality, including extensive training of health care providers and the development of tools to measure and assess quality improvement. Minimizing variations in practice and carefully collecting data on processes of care and outcomes requires multi-level changes to health systems.[12, 16, 17]

Quality improvement collaboratives (QICs) represent one systems-based approach to improve health care quality and patient outcomes. In 1998, the Institute for Healthcare Improvement developed the Breakthrough Series collaborative model, legitimizing a model for quality improvement and spawning new attempts to reorganize and improve care.[18, 19] In QICs, multidisciplinary teams from different sites work together to develop strategies to improve patient care.[2] QIC participants receive training in quality improvement, set measurable goals, track process and outcomes measures through plan-do-study-act cycles, exchange ideas and advice, and generate enthusiasm and commitment to achieving a common goal.[20] (Find additional information on the origin of quality improvement collaboratives in Appendix 1: Further Background on Quality Improvement Collaboratives.)

Health care providers and administrators have adapted QICs to fit their goals, from reducing hospital mortality associated with coronary artery bypass graft surgery[21] to lowering mean hemoglobin A1c levels in diabetic patients in primary care clinics.[22] Despite the face validity and growing popularity of QICs, investigators acknowledge the modest quantity and quality of evidence supporting collaboratives as an effective intervention.[20, 23-25] (Find additional information on the effectiveness of quality improvement collaboratives in Appendix 2: Limited Systematic Review of Quality Improvement Collaboratives.)

The Need for Quality Improvement in Pediatric IBD

Inflammatory bowel disease (IBD) affects greater than one million individuals in the U.S., including 100,000 children.[26] More than 700,000 physician visits, 100,000 hospitalizations, and disability for 119,000 patients are attributed to IBD annually.[27] IBD also presents a significant financial burden, with health care costs associated with adult and pediatric IBD exceeding $1.7 billion annually in the U.S.[26] Furthermore, pediatric IBD poses an additional psychosocial

burden on children and their families as children with IBD are at greater risk of difficulties in behavioral and emotional functioning.[28]

Like many chronic diseases, early studies suggest variation in care among IBD patients. In a study of 65 adult patients with IBD, Reddy et al. found that there was suboptimal dosing of maintenance medications, prolonged use of corticosteroids, failure to use steroid-sparing agents, and inadequate attention to metabolic bone disease and screening for colorectal cancer.[29] Colletti et al. reported similar variation in care among 246 pediatric patients with Crohn's disease.[3] Clinicians vary in their utilization of diagnostic interventions and treatments, including stool tests for pathogens, imaging of the small bowel, following pretreatment protocols before initiating thiopurine or infliximab, poor adherence to medication dosing recommendations, and inconsistencies in nutritional interventions among severely underweight patients.[3] As Kappelman et al. noted, "there is a clear need for translating evidence-based practices into the actual practice and follow-up provided for patients."[2]

ImproveCareNow (ICN) originated from the Pediatric IBD Network for Research and Improvement (PIBDNet), a two-year project funded by the North American Society for Pediatric Gastroenterology in 2004 to evaluate variation in care in pediatric Crohn's disease.[4] After publishing its findings in 2009,[3] PIBDNet shifted its focus to quality improvement and formed the PIBDNet Trailblazer Improvement Collaborative, basing it on the IHI's Breakthrough Series Model.[4] Beginning with ten sites in 2007, ICN has expanded to 23 sites with each bearing the costs of an annual participation fee to support the infrastructure of the collaborative, travel to semi-annual meetings of all the site teams, and staffing at its site for data collection and entry as well as quality improvement projects to redesign care delivery.[4] ICN has implemented a number of quality improvement activities to decrease variation in care, assess process and outcome measures, and track patients more efficiently. Collaborative members believe they have

witnessed promising results both in terms of processes of care and outcomes and think that practice sites are building sustainable infrastructures.

Investigators frequently demonstrate the need to lessen practice variation and improve the quality of care in many fields; however, they have a more modest understanding of how improvement happens in particular health fields, and know even less about how to sustain that improvement. Pediatric gastroenterologists have invested considerable energy, time, and finances to improve the quality of care of pediatric IBD patients through a quality improvement collaborative. The purpose of this project is to explore and assess the perceptions of participants in this preliminarily successful collaborative. Describing elements of sustainability of ICN has implications for future health delivery systems in its approach to other chronic diseases. I will examine the most valuable aspects of the collaborative, the obstacles to participation, and the variables affecting outcome measures perceived by ICN participants.

Methods

We used the following three methods of analysis to identify and verify perceptions of participation in ICN: (1) in-depth structured interviews, (2) a web-based survey of collaborative participants (see Appendix 3: Further Methods, and Appendix 6: Survey), and (3) observation of participants at an ICN learning session (see Appendix 3: Further Methods). This mixed-method analysis allowed us to triangulate our approach to accurately reflect the perceptions and characteristics of ICN collaborative participants. The University of North Carolina IRB reviewed our research protocols and determined that we were exempt from the consent requirement and from further review.

In-Depth Structured Interviews

The purpose of the in-depth structured interviews was to identify what ICN members believed were the key values, components, and drivers of the ICN collaborative and improved outcomes measures. Using process tracing, a method of obtaining information about well-defined and specific events and processes, elite interviews can be used to establish what a set of people think and to make inferences about a larger population's characteristics and decisions.[30] Elite interviews were used for additive purposes, or to provide new information that advanced the research process;[31] for our purposes, we used the information about interviewees' attitudes, values, and beliefs to develop a web-based survey.

Our sampling strategy was based on purposive and chain-referral methods, often used when randomized selection is not appropriate.[30] We selected a sample of participating centers that represented geographical diversity, differing lengths of membership in the ICN collaborative, and a range of public versus private practice settings. In total, we selected ten participating centers from the following hospitals and cities: Pediatric Gastroenterology and Nutrition Associates, Las Vegas, NV; Oklahoma University Medical Center, Oklahoma City, OK; Children's Hospital of Oakland, Oakland, CA; Nationwide Children's Hospital in Columbus, OH.; Maine Medical Center, Portland, ME; Inova Health System, Falls Church, VA; North Carolina Children's Hospital, Chapel Hill, NC; The Children's Hospital-Denver, Aurora, CO; Carolinas Medical Center, Charlotte, NC; and Children's Hospital Boston, Boston, MA. Seven of these sites had participated in the collaborative for more than two years; three were sites about to attend their introductory learning session. We contacted two members at each site using a standard recruitment message. First, we invited the principal investigator, always a physician at each site, whom we asked to identify a non-physician team member whom they felt could knowledgeably reflect on their center's experience of ICN membership. The interview protocols for existing and new ICN participants are located in Appendices 4 and 5, respectively.

At the beginning of each interview, we asked for the participants' permission to be recorded with a digital voice recorder and to use direct quotes for purposes of analysis. We recorded the interviews and used recorded files and type written notes to transcribe each interview. In total, we transcribed 42,780 words, equaling 91 typed pages. We sent each respondent his or her own completed transcription.

Methods for Coding Interviews. Based on a multi-step analytic method described by Philip Bernard,[32] two independent investigators (E.P and T.R.) systematically reviewed transcripts and notes from 16 interviews and coded them for themes and concepts in an Excel spreadsheet. Because interviews consisted of open-ended questions, we used an open coding strategy described by Strauss and Corbin[33] to construct our codebook. We began with 138 unique headings based on acquired knowledge and interview questions, which were collapsed into 19 larger categories. When new concepts emerged, we added a code heading to reflect them. To categorize particular responses, we sought to enter the respondent's "frame of reference," as described by Rogers.[34] Both investigators discussed and agreed upon establishing the final code headings. Then, we (E.P. and T.R.) independently reviewed the transcriptions and notes again to complete the codebook. We used 39 final code headings; codebook information can be seen in Table 1: Interview Data Collected.

Upon completion of coding, E.P. and T.R. met to determine the agreement in coding and resolve conflicts. Such utilization of multiple coding minimizes the potential biases when assigning categories to respondent data, and although intensive in nature, it leads to further refinement of code headings [35] and allow for more elaborate and through systematic analysis.[36] We used descriptive statistics to tabulate results in Excel. Kappa statistics for five sets of categorization headings are displayed in Table 2.

Results

Most Valuable Aspect of the Collaborative

Seventeen of 18 invited participants from ten sites agreed to be interviewed, and 16 of these 17 scheduled and completed the interview. Table 3 lists the interviewees and their member sites. Table 4 lists selected site characteristics. One participant refused to be recorded, and a second participant's interview was not recorded because of technical difficulties. The average interview lasted 24:46 minutes, but ranged from 10:09 to 43:07 minutes.

A summary of the most valuable aspects of the collaborative perceived by ICN participants can found in Table 5. Standardizing practice was the most common response among new site participants when they were asked to say what was most valuable to them as health care providers from joining the collaborative. One participant mentioned patient tracking as the most valuable aspect.

Participants from existing sites took varying perspectives. Three of the ten existing site participants claimed patient tracking was the most valuable aspect of ICN. Patient tracking can be summarized as a system that allows clinicians to track their patients' disease severity, diagnostic tests, nutrition and growth status, medications, and preventive-care measures. These participants describe the value of honing in on details of care they may miss otherwise. One key informant described the patient encounter when he realized the value of patient tracking:

> I've followed [one patient with ulcerative colitis] for 10 to 15 years…and I would see her about every 6 months to a year.... Over two or three years, she lost two to three kilos, …but because she didn't have …particular symptoms, I really didn't pursue it. But once we started up the collaborative…and watching nutritional status, …I started saying, 'Well, gee wiz, look at this, she's been going down for years!' …I re-evaluated her, and she had active disease, and when we started pushing, it became pretty obvious that she hardly ever took her medication.

Four existing site participants said that collaboration -- interaction with physician leaders, sharing information, and creating a sense of accountability – was the most valuable collaborative feature. For example, one informant describes the most valuable aspect of the collaborative as "being [able] to meet with … not only industry leaders and others that care for IBD [patients], but those that work in quality improvement as well. Having them meet in one spot has been invaluable." Another participant describes the sharing of information and resources in the collaborative: "People may have great ideas that you never thought of, and rather than re-inventing the things, let's adapt what's working well for other centers who do really well, while not wasting time repeating some of the same mistakes. The three remaining existing site participants described quality improvement training resulting in an increased knowledge base and resources, as the most valuable aspect of being in the collaborative.

Obstacles to Participation

ICN participants described encountering a number of obstacles during the implementation of particular ICN activities. Table 6 and 7 list barriers described by key informants and the frequency they mention them. Among new sites, participants worry that a number of factors threaten their participation in ICN quality improvement activities, the most common of which is time: three of the four new site informants mention their own time as a challenge to ICN participation. One provider expands: "Just seeing the huge volume of emails, I'm going to have to cancel a weekly clinic just to keep up. …The volume of communication seems to be quite significant. So, there has to be time, and someone has to pay for that time, right?"

Other barriers included a need for clinic infrastructure, fostering support from others in the practice, financial costs, a lack of personnel and resources, and a lack of understanding among other providers about what quality improvement is. Financial barriers may be particular to the type of institution a provider belongs. One provider says, "Every hospital is having

budgetary difficulties to support these research activities. We're not part of a university setting, so we have to find the money to pay the personnel that will be doing the study, to cover the budget for the trips to go and attend the meetings."

Providers at existing sites in ICN also worry about similar barriers: informants mentioned seven types of obstacles inherent to different ICN activities. Time was the most common obstacle (8 of 12 mentions), followed by earning the support for quality improvement from fellow health care providers (7 mentions) and a lack of personnel (5 mentions). Transitioning to electronic medical records and taking on too much work initially were two other challenges, with 3 mentions each. A single informant mentioned coordinating schedules and obtaining patient/family buy-in for a particular clinic change.

If we break challenges down by ICN activity, we see indications that particular challenges are inherent to the quality improvement activity. Table 8 provides a brief description of different ICN activities described by informants, and Table 9 illustrates the number of times a particular obstacle was mentioned in terms of a particular ICN activity. Population management, a form of patient tracking, was a commonly described collaborative activity and appeared to create a variety of challenges for providers, including time commitment, gaining the support of other providers, and working through personnel issues, such as a lack of providers or provider turn-over, often nurses. Pre-visit planning, the second most commonly described ICN activity, presents similar challenges to providers, though obtaining the support from other physicians in the practice was the most frequently mentioned barrier. Another notable activity that several sites have implemented is instituting an IBD clinic, which presents challenges unlike population management and pre-visit planning. Working through logistics and clinic restructuring was more commonly mentioned than time and gaining support from other providers.

Perceived Collaborative Effectiveness

When we asked collaborative members if increased patient remission rates were a result of the collaborative, 9 of 12 (75%) of the informants said "yes," and the remaining 3 said the ICN collaborative was partially responsible. Four of the 12 said that other factors were not affecting outcomes; half of participants were uncertain about the role of other influences, and 17% of respondents thought that outcomes were attributed to factors beyond collaborative activities. Respondents discussed sources of outcomes change: two informants mentioned variation in how patients were entered into the database, suggesting that, early on, sick patients were more likely to be enrolled given their frequency of clinic visits. Utilization of more aggressive treatment options was also mentioned by two informants. Subjective variation in scoring of disease severity using the Physician Global Assessment; inconsistent participation of other physicians at practices; natural stabilization of the course of disease over time, occurring independent of the collaborative; and disease characteristics not yet known by the medical community were all mentioned once.

Discussion

Performing qualitative interviews of ICN participants is the first step in understanding what health care provider perceive as the value, benefit, and challenge to initiating and sustaining quality improvement activities in a collaborative. At all points of the collaborative's evolution, health care providers must perceive that the collaborative and its activities provide tangible benefits to a practice. The differing views of the most valuable aspect of ICN by new and existing site participants may indicate that one's perception of collaborative value changes with increasing participation. For instance, new member providers may see a collaborative as an approach to establish care guidelines and build consistency in health care practices. Because developing Model of Care Guidelines, and measuring their implementation, was an

early focus of the collaborative, longer-standing members may have shifted their perceived value of ICN to patient tracking, collaboration with other providers, and quality improvement training. Alternatively, new member providers may not anticipate the value of collaboration, patient tracking, and quality improvement training at the onset of their participation.

Overcoming obstacles to collaborative participation cannot occur until the obstacles are identified. Because participants had not ever been queried about participation challenges in a systematic way before we conducted this study, collaborative leaders did not know to what extent particular barriers confront providers. Some challenges, such as financial costs, may not be surprising, but should be viewed in context of other obstacles facing providers. Sustaining quality improvement involves integrating it into the fabric of the practice, and gaining the support of non-ICN physicians for ICN is a substantial barrier.

In addition, challenges encountered by ICN members as they undertake particular ICN activities are also important to the sustainability of quality improvement activities. Most providers were in agreement about the value of population management and pre-visit planning, but often the continuation of these activities at certain sites is threatened by small changes, such as the turn-over or unavailability of a key provider.

Finally, and possibly most importantly, assuring that the collaborative itself is causing the increase in patient remission rates, a key outcome measure, is vital to sustaining ICN as an effective intervention. At this point, most providers believe the collaborative is the main driver of improved outcomes and this perception will likely sustain active collaborative participation and propel future recruitment of new sites. However, many ICN members are aware of potential confounders of measured outcomes. Though infrequent, participants' mention of confounders prompts further investigation into what other ICN participants feel may be influencing increasing remission rates and to what extent. Site-to-site variation in the perceptions of potential confounders is an important consideration for future quality measures. Overall, to ensure active

participation among existing and new members, most participants should agree that ICN is an effective approach to improving the quality of care provided to pediatric IBD patients.

Future Directions

These qualitative interviews serve as the foundation for a web-based survey that will allow us to measure more extensively the perceptions of ICN participants. The number of interviews completed for this project was not sufficient to make conclusive determinations regarding the perceptions of the universe of ICN participants. A web-based survey will allow us to reach the universe of providers, including various types of providers affiliated with ICN.

Two sites have withdrawn from collaborative participation since its inception. Examining the perceptions of former ICN members would give us a basis for comparison for several variables. For instance, do former ICN site participants feel that the collaborative did not provide valuable benefits to them as health care providers? Or, were there particular challenges that forced these sites to withdraw? Speculation points to the latter, but interviews with withdrawn site members could confirm this conclusion.

Multidisciplinary care is the basis for many quality improvement efforts, including the chronic care model and quality improvement collaborative. However, identifying the differing needs and obstacles facing different types of health care providers is also important to sustaining cross-disciplinary quality improvement efforts. Measuring the perceptions of other members of the IBD care team may shed some light on this question.

Conclusion

Quality improvement collaboratives are one approach to improving patient care, particularly with chronic disease management. The ImproveCareNow (ICN) collaborative is a network of pediatric gastroenterologists from public and private practices and different geographical regions who agreed to share outcomes data and information on processes of care

for the purpose of improving the quality of IBD care provided to their patients and families. Many investigators agree that reducing practice variation is an important step in quality improvement. Despite the great potential of collaboratives, investigators have a modest understanding of how improvement happens. In this project, we explored and assessed the perceptions of ICN participants about several aspects of the collaborative. In this paper, I presented results of qualitative interviews with 16 ICN providers specific to collaborative and quality improvement sustainability. For providers to be active members of the collaborative, they must perceive particular benefits, and results indicate that participant views of the most important aspect of collaborative participation changes over time. In addition, informants described various obstacles to participation in the collaborative itself and a number of its particular activities. Implementing and sustaining quality improvement takes much time, money, human resources, and provider commitment. Sustaining quality improvement requires systems change and commitment at all levels, at all times.

Tables and Figures

Table 1: Interview Data By Domain

Factor	Variables							
Interviewee	Name	Center	Existing/New site	Type of provider				
General Impression	Improve care for patients	Research opportunities	Interactions, accountability	Leadership, training skills	Developing best practices	Other		
Most Valuable Aspect	Patient tracking	Leadership training	Practice standardization	Other				
ICN Activities	Population management	Pre-visit planning	Standardized clinic template	Nutrition & growth algorithm	IBD Clinic	PDSA's	Multidisciplinary team meetings	Self-management
Activity Evaluation	Success	Order mention	Obstacles	Expectations	Implementation	HCP's involved	Practice standardization	Culture change
Determining Factors Contributing to Outcomes	Opinion of ICN	Confounders /Other contributors to outcomes	Other factors to be measured					
Obstacles	Budget	Lack of personnel	Creating a culture of QI	Time	Lack of leadership	Infra-structure		

Table 2: Kappa Statistics

Question	Kappa
Q1 – General Impression	0.57
Q2 – Most Valuable Aspect of Participation	0.83
Q3 – ICN Activity Categorization	0.82
Q4 – Outcomes Due to Collaborative	1.00
Q5 – Potential Confounders	0.62

Table 3: Interviewees

Name	Type of Practitioner	Center	City, State
Leslie Higuchi	MD	Children's Hospital Boston	Boston, MA
Victor Pineiro	MD	Carolinas Medical Center	Charlotte, NC
Deborah Neigut	MD	The Children's Hospital	Aurora, CO
Diane Redmond	Quality Improvement Specialist	The Children's Hospital	Aurora, CO
Sandra Kim	MD	North Carolina Children's Hospital	Chapel Hill, NC
Beth McLean	RN	North Carolina Children's Hospital	Chapel Hill, NC
Ian Leibowitz	MD	Inova Health System	Falls Church, VA
Bernadette Diez	NP	Inova Health System	Falls Church, VA
Mark Integlia	MD	Maine Medical Center	Portland, ME
Bernadette Ray	RN	Maine Medical Center	Portland, ME
Wallace Crandall	MD	Nationwide Children's Hospital	Columbus, OH
Amy Donegan	NP	Nationwide Children's Hospital	Columbus, OH
Sabina Ali	MD	Children's Hospital of Oakland	Oakland, CA
John Grunow	MD	Oklahoma University Medical Center	Oklahoma City, OK
Howard Baron	MD	Pediatric Gastroenterology & Nutrition Associates	Las Vegas, NV
Teresa Carroll	NP	Pediatric Gastroenterology & Nutrition Associates	Las Vegas, NV

Table 4: Selected Site Characteristics

Table Data	Site	IBD Patients Enrolled in Database		Direct Academic Affiliation	
		≤100	>100	Yes	No
Oakland = A	A	●			●
Las Vegas = B	B	●			●
Oklahoma = C	C		●	●	
Maine = D	D	●		●	
INOVA = E	E		●	●	
CMC = F	F	●			●
Nationwide = G	G		●		●
Denver Children's = H	H	●			
UNC = I	I		●	●	
Boston Children's = J	J	●			

Table 5: Most Valuable Aspect of the Collaborative Perceived by ICN Participants

Most Valuable Aspect of a Collaborative	Existing Site Participants (n=10)	New Site Participants (n=4)
Patient Tracking	3	1
Collaboration (Interactions with physician leaders, sharing information, creating a sense of accountability)	4	0
QI training	3	0
Practice Standardization	0	3
Other	0	0

Table 6: Obstacles to Collaborative Participation among New Site Participants

Obstacles to Participation (New Site Interviewees, n=4)	# Times Mentioned
Time	3
Need for infrastructure	1
Provider support for quality improvement	1
Budget	1
Lack of personnel	1
Lack of understanding about what QI is	1
Data collection difficulties	1
Resources	1

Table 7: Obstacles to Collaborative Participation among Existing Site Participants

Obstacles of Activity Implementation (Existing Site Interviewees, n=12)	# Times Mentioned
Time	8
Provider support for quality improvement	7
Lack of personnel	5
Transition to EMR	3
Taking on too much initially/getting in over our heads	3
Coordinating schedules	1
Patient/family buy-in	1

Table 8: ICN Activities & Descriptions

ICN Activities	Description
Population management*	An interactive program of patient tracking that allows providers to examine care provided to each site's IBD population across various multiple categories, such as disease severity, nutritional status, and treatment with selected medications
Pre-visit planning*	Process to identify upcoming patient visits and to plan those visits before the patient arrives
Standardized clinic template	Standardized clinic flow sheets that allow the physician to accomplish a set of goals at a clinic visit
Nutrition and growth algorithm*	An algorithm developed to assess nutrition and growth status at each patient visit and improve the management of patients with unsatisfactory results.
IBD Clinic	Implementation of a weekly, bi-weekly, or monthly clinic in which only patients with IBD are seen
Multidisciplinary team meeting	Team meetings made up of providers from various disciplines to discuss IBD patients. Often includes a physician, nurse practitioner, nurse, dietitian, and others.
PDSA cycles	Small tests of change particular to each site based on the Plan-Do-Study-Act model
Self-management*	Tools in the form of workbooks, seminars, CDs or DVDs provided to patients and parents to increase their knowledge of IBD and encourage greater disease management and medication adherence.
Model IBD Care Guideline*	Guideline developed to standardize diagnosis, disease monitoring, and treatment based on evidence and expert consensus

*Crandall, Kappelman, Colletti et al. In Press.

Table 9: Obstacles Mentioned by ICN Activity

Obstacles per ICN Activity	Population Management Report	Pre-visit Planning	IBD Clinic	Team Meetings	Standardized Clinic Template	ICN Data Collection	Nutrition Growth Algorithm
Time	4	3	1	2	0	1	0
Provider buy-in	3	5	1	1	0	1	0
Personnel issues	3	3	1	0	1	0	0
Transition to EMR	1	0	0	0	1	1	1
Logistics/ Clinic Restructuring	1	1	4	0	0	0	0

Appendix 1: Further Background on Quality Improvement Collaboratives

Origin of Quality Improvement Collaboratives

Promotion of quality assurance in the health care field originated long before the IOM reports *To Err is Human*[37] and *Crossing the Quality Chasm*.[14] In 1989, Berwick proposed the adoption of *The Theory of Continuous Improvement* in the field of health care.[38] However, for years few practitioners took quality improvement seriously because, as Kilo explains, promoters of quality assurance focused on cost control, did not know how to motivate physicians, had unrealistic expectations of health outcomes, and poorly understood the science of improvement.[19]

Nonetheless, Berwick's goals for improvement in health care[39] were the basis for the development of the Institute of Healthcare Improvement's (IHI) Breakthrough Series (BTS) collaborative model in 1998, which aimed to achieve "unprecedented levels of improved performance in participating organizations in less than 1 year by bringing providers together to understand and drive improvement within a specific topic area" (p. 2).[19] The IHI developed the collaborative model based on the following principles:

1. A sustained gap exists between knowledge and practice in health care;
2. Broad variation in practice is pervasive;
3. Examples of improved practices and outcomes exist, but they need to be described and disseminated to other organizations;
4. Collaboration between professionals working toward clear aims enables improvement;
5. Health care outcomes are the results of processes; and

6. Understanding the science of rapid cycle improvement can accelerate demonstrable improvement.[19]

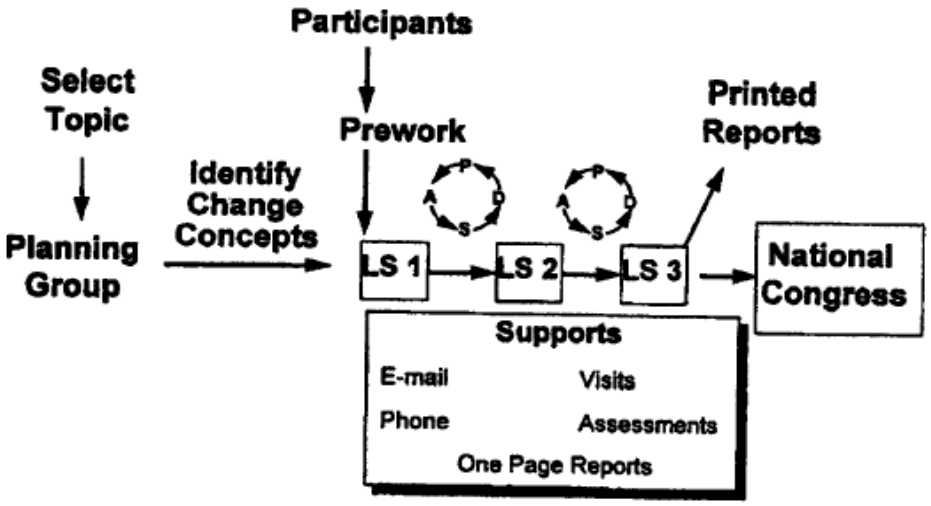
The IHI BTS collaborative model offered a framework adaptable for many types of diseases, provider networks, and health organizations. Wilson, Berwick, and Clearly [40] summarized the steps in the BTS Collaborative Model, which are presented in Figure A-1. The success or failure of collaborative is dependent on team member interactions, which take place during "learning sessions." Operating under a Plan-Do-Study-Act model, team members learn improvement techniques, exchange ideas and advice, and generate enthusiasm and commitment to achieving a common goal"[20] Learning sessions commonly involve specific instruction on improving selected aspects of care, developing, sharing, and refining data collection and tracking modalities, and reporting results or recent changes at each site.[41] After each learning session, team members return to their practice or organization to apply new knowledge and evaluate new outcome measures.[19] In between learning sessions, access to a listserv[41] or extranet is common, as are monthly conference calls. Some collaboratives also develop and utilize state- and region-based support, offering technical assistance to participating health centers.[42] Figure A-2 illustrates the basic framework of the BTS model.

Figure A-1. Steps of the IHI Breakthrough Series Collaborative Model

Steps in the Breakthrough Series Collaborative Model
1. Sponsoring organization identifies topics where a significant gap exists between best and typical practice.
2. The Institute for Healthcare Improvement (IHI) then assembles an expert panel.
3. Expert panel prepares a package of ideas for closing the gap.
4. IHI recruits participating teams to be part of the collaborative.
5. Participants engage in prework: forming a local improvement team, develop goals and measurements, and characterize current practice.
6. During a collaborative's life, usually 6-12 months, teams from participating organizations attend three learning sessions in which they learn about ideas for better practice and improvement methods that they implement between sessions.
7. Between learning sessions, teams share experiences and maintain contact through such mechanisms as conference calls and internet email listservs while submitting progress reports.
8. The lessons learned are spread through a national meeting (congress) and reports.

Source: Wilson T, Berwick DM, Cleary P. What do collaborative improvement projects do? experience from seven countries. *Joint Commission Journal on Quality and Patient Safety*. 2004;30(Supplement 1):25-33.

Figure A-2. IHI Collaborative Framework



LS: Learning session

Source: Kilo CM. A framework for collaborative improvement: Lessons from the institute for healthcare improvement's breakthrough series. *Quality Management in Healthcare*. 1998;6(4):1.

Appendix 2: Limited Systematic Review of Quality Improvement Collaboratives

Introduction

Investigators have identified deficiencies in the safety and quality of health care provided in the U.S. [14, 37] Among recommendations proposed by the Institute of Medicine's *Crossing the Quality Chasm* is one promoting collaboration among clinicians, institutions, and patients through shared knowledge, free flow of information, evidence based decision making, and transparency of health system processes.[14] In addition, financial rewards linked with clinical outcomes further incentivize adoption of quality improvement methods.[43] Quality improvement collaboratives (QICs) represent one systems-based approach to improve health care quality and patient outcomes.

The purpose of this review is to provide an overview of the literature surrounding QICs, to classify the types of analyses performed on chronic disease QICs, and to appraise the quality of literature examining their effectiveness. First, we will briefly describe the evidence base for QICs. Then, we will report the methods, results, and discussion of a systematic review of studies examining collaboratives specifically focusing on chronic disease. Finally, we will outline suggestions for future research.

Evaluation of the Evidence Base Surrounding QICs

Since the inception of IHI's BTS collaborative model, various health care systems, organizations, and groups of providers have adopted versions of collaboratives to fit their needs. Improving surgical and critical care outcomes in hospitals were among the first targets of collaboratives. Early quality improvement collaboratives included the Northern New England Cardiovascular Disease Study Group,[21] the US Veterans' Affairs National Surgical Quality Improvement Program,[44] and the Vermont Oxford Network,[45] which aimed to improve hospital mortality associated with coronary artery bypass graft surgery, morbidity and mortality rates

after major surgery, and quality of care for very low birth weight infants neonatology survival rates, respectively.

Utilization of collaboratives quickly expanded from hospital-based outcomes to outpatient-based diseases and illnesses. As of 2003, the IHI had conducted collaboratives with over 700 teams working on 23 clinical conditions.[41] In addition, the U.S. Health Resources and Services Administration[46] and the Veterans Health Administration[47] adopted the QIC method. Moreover, adoption of collaboratives expanded beyond the Unites States. Australia, France, the Netherlands, Norway, Sweden, and the United Kingdom's National Health Services have developed and implemented variations of collaborative programs.[40]

Numerous studies document the effectiveness of particular quality improvement collaboratives (QICs). Investigators credit the implementation of QICs for reduced inpatient mortality rates associated with coronary artery bypass graft procedures,[21] decreased neonatal infection rates,[48] decreased c-section rates,[49] less costly prescriptive practices,[50] improved patient safety,[50] decreased emergency department waiting times,[51] and improved management of patients with chronic disease.[50 52] Such studies support the use of quality improvement collaboratives as a viable method for identifying and implementing best practices.

Few studies in the literature conclude that QICs are ineffective, but Landon and colleagues[41] offer one example. They performed a prospective matched pre- and post-interventions study of almost 10,000 HIV-infected patients and found that a multi-institutional quality improvement collaborative did not significantly affect the quality of care.[41]

Other studies sought to identify and explain components of successful collaboratives, which often take the form of informant interviews. Ayers and colleagues[53] used open-ended questions of 18 key informants involved in successful data-driven quality improvement learning collaboratives in the U.S. and Europe. They identified the following patterns: cultivating trust,

attendance to the human dimension, nonlinear development, attendance to organizational culture, integrated philosophy of quality improvement, and a focus on process and outcome measurement to drive change.[53] Meanwhile, Wilson and colleagues[40] performed semi-structured interviews with 15 leaders of collaboratives to ascertain the features of effective collaboratives; they identified the following seven critical determinants: sponsorship, topic, ideas for improvements, participants, senior leadership support, preliminary work and learning, and strategies for learning about and making improvements.[40] However, the internal validity of these studies is questionable because of variation in collaborative frameworks, which targeted a diverse set of medical outcomes and settings, ranging from ambulatory care to critical care units. Similar inconsistencies are rampant in the QIC literature.

Methods

We conducted a MEDLINE search to search for literature written about chronic disease QICs published before January 2010. The search algorithm appears in Figure A-3. We used the following MeSH terms: "quality" AND ("cooperative behavior" OR "cooperative" AND "behavior" OR "collaborative") AND "improvement." Our 2-person team reviewed the titles and abstracts of articles appearing before January 9, 2010. To obtain additional articles not recovered in our MEDLINE search, we hand-searched references of sentinel articles.

We included studies that were written in English, took place in the U.S., examined collaboratives targeted at one or more chronic diseases, and met the definition of collaborative. In an *ad hoc* manner we defined a quality improvement collaborative (QIC) as "a voluntary network of health care providers in more than one health care system, who agree to share data and information on processes of care for the purpose of improving the quality of care and patient outcomes." This definition was based on a pilot search and review, which identified important components of these interventions as including identification of variations in care or

deviations from published guidelines, defined, measurable outcomes, a willingness to pursue active information sharing, and collection of data with the intent to study the effectiveness of the intervention. These variables, and others, were also identified in a systematic review of collaboratives by Schouten et al, which helped add a measure of validity to our original search goals and inclusion criteria, for quality improvement collaboratives.[54]

We excluded articles if the collaboratives took place in the settings of improvement in emergency departments, intensive care units, and primary care practices not focusing on a particular chronic disease. We also excluded articles written about collaboratives focused on organ donation, general preventive measures, medical imaging, surgical interventions, and palliative care.

From abstracts and full-texts of the articles meeting inclusion and exclusion criteria, we extracted the following information: the authors and year of the publication, the disease or medical specialty (i.e. pediatric cardiology, psychiatry, etc.) addressed in the collaborative, the setting of the collaborative participants, and the type of analysis performed by authors. We then classified the types of analyses into the following three broader categories: process and methods, sustainability, and effectiveness. *Process and methods* included articles written about the need, development, and implementation of quality improvement collaboratives. The category of *sustainability* included articles that described or identified internal or external resources necessary to sustain the effects of a collaborative. Among these, we also recorded if authors addressed the importance of team work or informatics as necessary components of the collaborative investigated. Finally, the category of *effectiveness* included articles that evaluated the effectiveness of collaboratives on patient outcomes.

Next, we appraised the quality of studies measuring the effectiveness of QICs. We reviewed the articles classified in the category of *effectiveness* for studies reporting patient-

oriented outcomes. We excluded studies evaluating effective components of a collaborative, i.e. teamwork or information technology, and studies examining exclusively non-disease specific outcomes. From the studies meeting these inclusion and exclusion criteria, we extracted the following information: the disease or medical condition addressed by the collaborative, a brief description of the study, the study design, the participants in the analysis, the source of assessment, the outcomes assessed, the methodological status, the duration of follow-up, and the findings. For each study, we appraised the internal validity, external validity, and the clinical utility of the measured outcomes.

Results

The MEDLINE search algorithm produced a total of 626 articles, but only 51 met inclusion criteria. A hand-search of pertinent literature yielded five additional articles. Table A-1: Literature for Systematic Review details the classification of the 56 articles. Nineteen fell into the category of process/methods, 15 in sustainability, and 22 in effectiveness.

Categories of Literature

Process/methods articles focused principally on the formation and evolution of the development of collaboratives. If collaboratives were new to a particular medical field, such as pediatric cardiology or pediatric gastroenterology, investigators published articles outlining the need for a QIC and often detailed an adapted model to suit the goals and needs of the field. Other process/methods articles focused on the implementation of a collaborative or evaluated the implementation by measuring clinic or physician practices.

Articles classified under the categories of sustainability and effectiveness reported various outcomes about collaboratives that had been in operation for at least one year. In general, sustainability articles reported the necessary components to sustain the quality improvement practices initiated because of a collaborative. Some investigators addressed sustainability of a collaborative itself, while others focused on specific components of the QIC. To evaluate which components of a QIC were effective, investigators often conducted qualitative methods, such as interviews with key informants. Six sustainability studies[55-60 61] mention information technology as a necessary component, while 4[55-58] of these specifically evaluate a particular type of technology utilized in the collaborative. Three sustainability studies[60-62] cited an element of teamwork as an effective QIC component. One study evaluates the cost-effectiveness of implementation of a QIC.

Investigators evaluated a variety of outcomes of collaboratives in studies classified in the category of effectiveness. The outcomes examined are as diverse as the goals for initiation of collaboratives. For instance, some QICs aim to reduce disparities among diabetic patients, while others evaluate physician practices and patient-outcomes.

Unsurprisingly, most collaboratives address common health conditions, such as heart failure, diabetes mellitus, asthma, and depression. QICs focused on HIV and stroke were also common. Unique medical topics included urology and COPD. Pediatric illnesses were also represented in the chronic disease QIC literature. Common pediatric conditions or topics addressed included asthma, inflammatory bowel disease, development disorders, cardiology, and rheumatology.

Critical Appraisal

A summary of the systematic review of QIC effectiveness studies is provided in Table A-2: Critical Appraisal. Overall, 13 manuscripts met the inclusion criteria for the systematic review of the effectiveness of QICs. [41, 42, 63-67, 67-73] Of these, only 3 studies involved a randomized component in their study design. Five included studies [41, 42, 63, 64, 70] used a comparison group study design, with selected intervention sites and control sites, not unlike a case-control design. Three studies[66, 67, 70, 72] used quasi-experimental before-and-after designs, one[73] used a cross-sectional analysis of a state's health plans, and two studies[65, 68] were uncontrolled cross-sectional analyses of a single site participating in a collaborative intervention.[73]

Randomized Studies

Two of the studies featuring a randomized component[69, 71] used a cluster randomized controlled trial design, randomizing at the practice level to assess the intervention. One study[67] was designed primarily as a quasi-experimental before-and-after design, but randomized selected centers to either standard or high-intensity collaborative interventions, the latter involving four additional learning sessions and provider training. On the whole, none of these randomized trials or arms found that collaborative quality improvement interventions led to improved outcomes.[67, 69, 71] One study randomized forty-three practices in greater Detroit and greater Boston to participation in a learning collaborative based on Breakthrough Series methodology or standard care.[69] For children with asthma, Homer et al. found no significant improvements in asthma process-of-care outcomes, clinical outcomes, or utilization outcomes for individuals randomized to the intervention group.[69] Another randomized study,[71] undertaken by Philbin et al., randomized ten hospitals in the upstate New York. Intervention hospitals received an intensive, multifaceted quality improvement intervention consisting of educational

sessions, critical pathways, and lectures. The New York research team found no significant improvements in process-of-care markers or clinical outcomes among intervention sites compared to controls. However, a slight, non-significant reduction in hospital length-of-stay was observed among intervention hospitals. The third and final study with a randomized component that fit our inclusion criteria was a study of a diabetes quality improvement collaborative, undertaken by Chin et al.[67] Embedded in a longitudinal study looking at the effect of a collaborative quality improvement intervention for, sites treating patients with Type 2 diabetes were randomized to either a high-intensity and standard protocol after 1-2 years of participation. For ACE inhibitor and aspirin use, Chin et al. found slightly higher documented rates of compliance.[67] However, for many other intermediate incomes, and for clinical outcomes measures, there was no significant effect of the higher-intensity intervention.[67] For several of the intermediate outcomes, including HbA1c levels and systolic blood pressure measurements, control sites out-performed sites that participated in the high-intensity intervention.

Observational Studies

The majority of the studies included in our review were observational studies, employing several different designs. The preponderance of observational study designs among our included studies mirrors the predominance of non intervention-based, observational studies in the literature on collaboratives. Four studies[41, 42, 63, 64] that met inclusion criteria for our report were observational studies molded as case-control studies at the practice level. These studies, offering fewer statistical limitations and theoretically fewer potential confounders and biases in their study design than simple before-and-after studies, represented the most common type of study included in our report. Asch et al. studied the effects of a BTS collaborative on heart failure outcomes and found a significant positive effect of collaboratives on counseling and

education outcomes, as well as positive effects on rates of ACE inhibitor and lipid-lowering therapy for heart failure patients. However, Asch et al. found no improvement in readmission rates for patients at participating sites.[63] Landon et al., in 2004, published results from a similar assessment of a BTS collaborative, this time concerning HIV treatment and quality. Comparing 44 intervention sites to 25 control clinics primarily on the basis of control of viral load and prevention of opportunistic infections, investigators found no significant differences in outcomes between the two groups. Although the end result was a lack of significance, the proportion of patients with viral load controlled increased twice as much in the intervention group compared to the control group; these figures were 11.0% improvement (40.7 to 51.7) and 5.4% improvement (44.1 to 49.5), respectively.[41]

Despite mediocre results in the EQHIV study, another Landon-led research team assessed the effects of collaboratives on management and outcomes of asthma, diabetes, and hypertension.[42] Interestingly, for these common chronic diseases, Landon et al. found that collaborative participation was associated with improvements in screening, prevention, and disease monitoring, for patients with asthma and diabetes.[42] Similar improvements were not seen with hypertension, however. For diabetes and hypertension, there was virtually no effect of collaboratives on clinical outcomes. In contrast to these results, Baker et al. found that participation in a collaborative for heart failure reported much higher quality of life, satisfaction with medical care, and knowledge of their condition.[64] Most importantly, patients in the intervention group utilized less care, in terms of hospitalizations, than those in the control group.[64] Despite selection concerns in this study, the utilization outcomes data shows that meaningful improvement likely did occur. The final study comparing "intervention" sites to selected control sites assessed the effects of a quality improvement collaborative on quality of care and outcomes for childhood asthma. [70] Comparing nine intervention sites with four control sites, Mangione-Smith et al. found significant improvements in process-of-care measures and

patient self-management skills. However, small differences in health utilization outcomes between the two groups were not statistically significant, echoing the non-significant findings of this type in several other studies.[42, 72]

Of the remaining studies that fit our inclusion criteria, three employed a before-and-after design, one analyzed variations in care from the perspective of a state health plan, and two studies were uncontrolled studies, reporting results and experiences related to a single site's participation in a collaborative. Two of the before-after studies targeted Health Disparities Collaboratives (HDCs). Both of these [66, 67] studied the effect of collaborative interventions on diabetes care, using a collaborative structure that emphasized involvement of community health centers, combining semi-structured interview data with surveys and reviews of medical records. In these studies, investigators found significant improvements across the board, from process-of-care measures such as HbA1c checks, foot and eye exam referrals, and lipid assessments, as well as HbA1c control, an intermediate outcome that for diabetes surves as a monitor for disease control. Between the two studies the improvement in HbA1c ranged from 0.2%[66] to 0.45%,[67] although this difference was not significant in either case. The third study with a before-after study design[72] actually included control sites for comparison, but the control sites had dramatic differences in location and payor mix compared to intervention sites, so for the purposes of this analysis the study was treated as a time series analysis. Schonlau et al. found several significant differences between intervention clinics and control clinics, including several satisfaction and self-management indicators.[72] With only 9 included centers, however, the number of utilization outcomes or events (e.g., emergency room visits) was very small, preventing investigators or readers from reaching meaningful conclusions from the results. For example, during the 13 month period of the study, in the intervention group there were two emergency visits by patients during the study (according to survey data), compared to a single ED visit among control patients.[72]

One study[73] that met our inclusion criteria found positive gains attributed to a statewide collaborative for Diabetes quality improvement. Reported from the perspective of Wisconsin-based HMO health plans, Siomos et al. found incremental improvements in LDL and HbA1c monitoring, nephropathy screening, and eye exam referrals. However, absent in this study were descriptions of which HMO plans were included for each year of analysis as it varied according to year, and was not explicitly tracked. Nor was there included information on selection of sites, clear presentation of results, or analysis of findings. The final two studies that met our search criteria[65, 68] had similar validity questions, stemming from incomplete and haphazard reporting of results, no arrangements or discussion of secular trends, and lack of demographic information on included patients or sites. In addition, Benedetti et al. and Fox et al. presented select information on only one participating center, which drastically limits the validity of these studies. With no substantive discussion of secular trends, the primary purpose of these studies was informative. From an appraisal standpoint, however, these two studies do little to prove that quality improvement collaboratives have a positive, meaningful effect on quality of care and outcomes.

Discussion

The literature on chronic disease QICs is appropriately diverse to coincide with the variety of chronic diseases and conditions and the range of goals QICs seek to address. For instance, the heterogeneity of HIV patients seen at outpatient care facilities may require completely different management strategies from visit to visit. Thus, an HIV collaborative may be less fitted to a rigorously systematic, QIC methodology.

The three categories of process/methods, effectiveness, and sustainability represent the natural evolution of QIC literature. Investigators will continue to report adapted QIC processes

and methods for different conditions. Next, collaborative participants must measure patient outcomes and determine what components of the QIC contribute to those outcomes. Finally, identifying and developing methods to sustain quality improvement is crucial. The literature thus far indicates chronic disease QICs are at an early evolutionary stage.

In particular, investigators need to measure consistent patient outcomes to strengthen the evidence of effectiveness of chronic disease QICs. Doing so requires reliable and valid quantitative medical research designs. However, the transition to evaluation of effective QIC components and how to sustain them likely requires qualitative research methods, which may be a challenge for clinical investigators unfamiliar with such methods.

An appraisal of the chronic disease QIC effectiveness literature reflects poor internal validity. Randomized controlled trials have the greatest potential to maximize internal validity, but they are rare in the literature. We did not find consistent, corroborated evidence proving the effectiveness of collaboratives.

There are several limitations of these studies that both weaken the strength of the results and highlight the difficulties inherent in effectiveness research on quality improvement collaboratives. Unfortunately, conducting assessments of practice-based interventions is quite difficult, especially for the purposes of directing public policy or solidifying a research base that meets commonly referenced reporting standards. Utilization of non-randomized studies, up to this point unofficially, as the primary method for proving the effect of collaboratives on improving the quality of care is fraught with hazard.[23] Put simply, the greater the concern about the methodological quality of some of these studies, the less we know that their results are valid. For example, when only a small fraction of sites participating in a collaborative volunteered to be studied as intervention sites, there were many ways for that sample to be a non-representative one. Leaders at underperforming sites participating in a collaborative, especially with data

collection aids, likely were aware of their sites' relative poor performance, and may not have volunteered for a study because of their own inherent belief that collaboratives are beneficial. Randomization affords the investigator the opportunity to account for both known and unknown confounders, and with special relevance for collaborative-based interventions, has the potential to eliminate biases associated with secular trends. Still, RCTs are not immune to biases, and what follows is a discussion of limitations associated with the randomized studies that analyzed the effectiveness of collaboratives.

In the study by Homer et al.,[69] a much higher percentage of patients enrolled in control sites were on Medicaid. In addition, as reported by the study authors, the risk of contamination in the study was high. This arises from the fact that although 43 sites were randomized at the start of the study, representing the largest sample of clinics included in our review, all forty-three practices were located in one of two geographic areas. In one of the studied regions (Detroit, MI), all of the participating sites, regardless of control or intervention status, were under the same ownership. An unknown dilution factor could have assimilated the medical practice of intervention and control sites that happened to employ the same physicians, but the effect this had is uncertain. In addition, there is no way to ascertain the level of participation or commitment at each site, given that sites were randomized, and some sites with limited investment in the project may have diminished the magnitude of effect at certain sites.

Another randomized study, undertaken by Philbin et al.,[71] randomized 10 practices to either an intensive quality improvement intervention or standard care, for patients with heart failure. This study was exposed to fewer potential biases than the earlier study, primarily due to minimal contamination concerns, but had limitations of its own. First, blinding was not maintained during the study. In addition, as is the case with the other randomized studies, it is difficult to know what effect any secular trends, among the control sites, may have had. Further, as with other randomized study designs analyzing the effect of practice-level interventions, it is

very difficult to ascertain the intent or strength commitment of participating clinics and their leaders and practitioners. Leadership is an oft-mentioned component of successful quality improvement and collaborative interventions.[47, 74] Additionally, although Philbin et al. made heart failure the focus of their study, the primary evaluations were carried out from the perspective of acute inpatient diagnosis and treatment, rather than chronic outpatient care.

The final study that included a randomized component in the study design was conducted by Chin et al.[67] The randomization to either standard-intensity intervention (with no additional learning sessions) or the high-intensity intervention (attendance at 4 additional learning sessions) did not give any significant differences between groups. However, there are several reasons why a true benefit to collaborative interventions might have been missed here. First, even though the study used randomization, it is vital to note that randomization occurred 1-2 years into the study, at which time *all included sites* had been participating in the longitudinal, observational study, attending collaborative learning sessions, and engaging in quality improvement measures.[67] Thus, a majority of the attainable improvement may have already been reached by the time of randomization. In addition, as is the case with the vast majority of studies on collaborative interventions, documentation variation plays as substantial role in the perceived effectiveness of collaboratives, in many of these study designs. In this particular study, the high-intensity intervention was associated with less documentation of diabetes education and exercise counseling. However, additional attention to medication adjustments and communication may have left less time for counseling in a short clinic visit. Or, physicians may have continued with counseling but spent less time documenting so in medical charts. The uncertainty with documentation issues like these clouds a final judgment of effectiveness of the high-intensity intervention.

The longitudinal study published by Chin et al. in 2004[66] as well as the longitudinal study (with the embedded randomized component) published in 2007[67] both are burdened with a

serious validity concern that affects any before-after study of this type. Unlike the more sophisticated interrupted time series design[75] that employ time series regression models to reduce unwanted bias in their design, before-after or time-series designs have few defenses against the risks of secular trends. In a health care environment with increasing awareness of quality of care and quality improvement, especially since the release of the IOM reports, the potential effects of secular trends are substantial. During observational studies like these, unknown and unstudied events can occur at any subset of participating sites, drastically weakening the ability of readers to make causal inferences about their results.[75] Internal validity can easily be compromised, especially if studies essentially conduct two-sample t-tests on pre-intervention points and post-intervention points. Doing so gives inaccurate effect sizes if pre-intervention trends are present.[75]

Certainly, not all observational should be judged equally. Achieving improved quality of care for HIV patients, as discussed in the EQHIV study,[41] in many ways represents a more difficult challenge than doing so for patients with chronic cardiovascular disorders, such as hypertension or diabetes. At any particular site in the EQUIV study, especially in a non-randomized environment, variation in follow-up, medication adherence, and insurance status, could conceivably have a larger effect on care outcomes than the actual care received in the clinic. Adherence to anti-retroviral medications, for example, is directly correlated to HIV viral load, although adherence could be a confounding variable in a non-randomized study. In addition, socio-economic and demographic characteristics of the patient population, clinic organizational cultures, and financial and regulatory issues make the task considerably more complex.[76] Landon et al. attempted to account for known confounders by matching intervention sites to control sites according to several criteria. Rigorous observational study designs like the EQUIV study can be useful, although currently there is no method for assessing the role of leadership at participating sites. Although it is potentially just as problematic in randomized

studies, since sites with strong leadership could all be randomized to control sites, the effect of a quality improvement "champion" or leader at sites participating in a collaborative is universally understood and valued by those with collaborative experience.[19, 74] Sites without motivated leaders may consistently underachieve compared to centers with strong leadership. Unfortunately leadership is difficult to assess in these studies.

Another problematic issue when analyzing and interpreting the literature on the effectiveness of collaboratives is the almost universal reliance on medical records for data collection. As discussed previously concerning the randomized intervention undertaken by Chin et al, this problem drastically undermines the ability to draw conclusions from uncontrolled studies,[65, 68] in which simply increasing documentation in a practice or practices can give the impression that large improvements in care have occurred. But even for more sophisticated studies, determination of statistical significance from medical records alone is troubling. If, for example, a learning session emphasizes preventive counseling and lifestyle changes for heart failure, does finding a higher percentage of patients with "dietary counseling" in their chart indicate quality improvement? For evaluation of prevention and screening measures, an undocumented test or discussion is one that for the purposes of analysis did not occur. Further, in practice-based intervention studies where blinding is seldom performed, an increased emphasis on documentation may falsely create the sense of improvement when the only improvement has been documentation itself.[64] This apparent effect may be embellished further by investigators who, although they have the best of intentions, are invested in collaborative methods and intrinsically believe in their value. Although not a central point in published guidelines for reporting observational studies,[77] blinded, dual review is a vital component of systematic reviews and dual review could potentially be used to increase the validity of these types of studies. Such a measure would not eliminate potential biases that can arise from review of medical records, however.

Still, an important distinction about medical record abstraction should be made here, because some endpoints can be reliably taken from medical records. One of the most important uses of medical records is making a determination of definite clinical outcomes, such as MI, stroke, death, or other conditions that are easily defined and reliably documented. However, of the 14 studies we evaluated that analyzed the effect of collaboratives on chronic disease care, only 6 (or 43%) even collected data on clinical outcomes. Data tables in these articles are filled with satisfaction measures, quality of life indices, and process-of-care targets, some of which are linked to improved outcomes. However, higher indicators now do not equal improved outcomes in the future. Whereas there can be disagreement among scales and indices when researchers assemble them together to make a clinical judgment, as in a meta-analysis, there is no dispute when studies publish hard, easily defined, concrete outcomes. Of course, improving quality of care is not limited to keeping patients alive, and true quality includes many of these components. In addition, the current medical record abstraction method for data collection in these practice-level interventions is quite useful for some conditions. For instance, heart failure is a condition that arguably is quite better suited to medical record abstraction. For heart failure patients, unlike patients with other medical conditions, utilization outcomes can be used as a proxy measure for disease control. With diabetes mellitus, the pathological processes underlying the disease are often undetectable to afflicted patients, and long-term adverse events like heart attacks, strokes, and peripheral vascular complications are most commonly measured. For heart failure, a poorly controlled patient is a symptomatic one, who will likely present to the hospital with more short-term needs.

Future Directions

Despite the hope that collaboratives do improve care enough to lead to improvements in satisfaction, processes of care, and self-management, the evidence linking these changes to

improvements in patient outcomes is somewhat underwhelming. With these limitations, however, come opportunities for improvement, and there are other indications that collaboratives may be more successful than the demonstrated evidence currently indicates. For instance, many collaboratives are currently ongoing. Although funding constraints and logistical issues have prevented long-term data collection and analysis for the purposes of publication, these opportunities will increase the future.

Although the literature to date contains some methodological flaws, the sense of cooperation, information-sharing and camaraderie that these interventions can create, both between sites and within sites, is likely already leading to improved care. In a recent study by Bray et al, researchers found that even once a collaborative project with a defined-length of operation ended, many of the quality improvement programs, from infrastructure support, regular meetings to study patient data, and leadership development, remain in place at participating clinics.[61]

QICs are likely to become more frequent in pediatrics as the American Academy of Pediatrics now requires participation in quality improvement projects. In the Education in Quality Improvement for Pediatric Practice (EQIPP) program, qualified improvement projects help distribute practice-wide data on effectiveness and management.[78] Enrollment in such a program allows one to receive credit that is required under Maintenance-of-Certification guidelines for Pediatricians. Collaboratives may be beneficial to streamline practices, implement efficient data management strategies, and improve patient tracking, but they are not equally suited to all diseases treated in an outpatient setting. Investigators and researchers must systematically define, through assessments of performance outcomes and medical record audits, which disease processes are more amenable to collaborative interventions and which are less so.

The gaps remaining in the literature must be addressed by subsequent investigators. As mentioned earlier, current medical management of certain chronic diseases are unclear and must be defined. Such a step requires commitment of regulatory agencies and professional medical associations alike. An effort should be made to increase the number of facilities involved in these interventions, to strengthen the ability of statistical techniques to show significant conclusions. In addition, an increased number of included clinics, from various geographic, socioeconomic, and organizational styles, must be approached and included.

Second, key investigators and journal editors must establish standards for research design and methods for evaluating collaboratives to ensure reliable, valid, and comparable findings, which may facilitate future systematic reviews and meta-analyses.[20] Third, sponsoring agencies of QICs need to provide more information regarding the teaching and implementation of collaboratives.[41] The IHI BTS collaborative model provides the most detailed information on collaborative start-up; however, many variants exist. Additionally, BTS collaboratives were designed to last one year or less and offer little direction for providers once a particular collaborative is over.

Finally, quality improvement remains a complex issue in health care. If inconsistent research designs prevent the identification of successful components of QICs, then the components necessary to sustain quality improvement following the completion of a collaborative is less certain. An evidence base for quality improvement itself must be improved. Future research must address concepts regarding the nature of quality problems, quality improvement processes, and the types of research needed to elucidate these processes.[20]

As the push for improved health care processes and patient outcomes continues, quality improvement collaboratives present a popular method to develop best practices, which may shape future payment systems. Collaboration between like-minded physicians can increase

camaraderie, facilitate data, speed the adoption of best practices, and most importantly, improve care for patients with chronic disease. However, the research methods to evaluate collaborative interventions require a different mindset, and standards different from those required of a drug trial or biochemical assay. As interventions effecting practices, collaboratives are tests of teamwork, leadership, and commitment. With a renewed emphasis on patient care and best practices, the true effect of these QI interventions remains to be seen. Until then, collaborative interventions may represent some of the most ambitious efforts to change outpatient care delivery for patients with chronic diseases.

Table A-1: Literature for Systematic Review

Article	Year	Medical Topic/ Condition	Category	Setting
Asch, et al.	2005	Congestive Heart Failure & Diabetes Mellitus	Effectiveness	4 IHI BTS participating health care organizations & 4
Baker, et al.	2005	Heart Failure	Effectiveness	6 health care organizations participating in an IHI BT collaborative
Ballard DJ et al.	2002	Diabetes Mellitus	Effectiveness	22 primary care practices in a network owned by Ba Care System
Benedetti, et al.	2004	Diabetes Mellitus	Effectiveness	Sites participating in a Washington state diabetes co
Bonomi AE et al.	2002	Congestive Heart Failure & Diabetes Mellitus	Effectiveness	108 organizational team from across the US active i QICs
Chin MH et al.	2007	Diabetes Mellitus	Effectiveness	24 health care centers in the Health Disparities Colla 2 years
Chin MH et al.	2004	Diabetes Mellitus	Effectiveness	19 Midwest health centers
Cretin S et al.	2004	Diabetes, CHF, asthma, depression	Effectiveness	37 participating organizations, 22 control sites
Fox J et al.	2006	Acute MI & Heart Failure	Effectiveness	5 hospitals in Wichita, KS
Homer, et al.	2005	Pediatric Asthma	Effectiveness	43 clinics in the greater Detroit & Boston areas
Johnson EA et al.	2005	Diabetes Mellitus	Effectiveness	40 primary care practices in 3 rural states
Katzelnick DJ et al.	2005	Depression	Effectiveness	20 ethnically & geographically diverse health care o
Landon BE et al.	2004	HIV	Effectiveness	44 intervention clinics & 25 matched control clinics
Landon, et al.	2007	Diabetes, Asthma, Hypertension	Effectiveness	Community health clinics in the Health Disparities C
Mangione-Smith R et al.	2005	Pediatric asthma	Effectiveness	13 primary care clinics
Meehan TP et al.	2004	Hypertension	Effectiveness	17 primary care practices treating Medicare patients
Otley AR et al.	2006	Pediatric Inflammatory Bowel Disease	Effectiveness	18 US & Canadian centers
Philbin EF et al.	2000	Heart Failure	Effectiveness	10 acute care community hospitals in upstate NY
Schonlau M et al.	2005	Asthma	Effectiveness	6 intervention clinics & 3 matched control sites in an collaborative
Siomos EE et al.	2005	Diabetes Mellitus	Effectiveness	Managed care plans participating in state diabetes c
Stoeckle-Roberts S et al.	2006	Stroke	Effectiveness	13 Michigan hospitals in a stroke collaborative
Swanson KA et al.	2007	Depression	Effectiveness	Sample of 11 of 108 community-based health care c in a national depression collaborative
Boratgis G et al.	2007	Heart Failure & others	Process/Methods	3 collaboratives addressing chronic disease or chro
Bousvaros A et al.	2006	Pediatric Inflammatory Bowel Disease	Process/Methods	N/A
Britton LF et al.	2008	Pediatric Cystic Fibrosis	Process/Methods	1 center of 14 receiving a CF collaborative grant
Deprez R et al.	2009	COPD	Process/Methods	18 primary care clinics in rural Maine
Fitzgerald E et al.	2005	Psychiatry	Process/Methods	NJ state mental health services & psych hospitals
Jenkins KJ et al.	2008	Pediatric Cardiology	Process/Methods	Various centers involved in pediatric cardiology colla

Kristofco RE & NM Lorenzi	2007	Depression	Process/Methods	23 ethnically & geographically diverse health care o
Kugler JD et al.	2009	Pediatric Cardiology-Hypoplastic Left Heart Syndrome	Process/Methods	Members of the Joint Council on Congenital Heart D
LaBresh KA et al.	2006	Stroke	Process/Methods	Members of a national stroke registry
Mandel KE et al.	2007	Pediatric Asthma	Process/Methods	44 pediatric practices in an asthma improvement co
McInnes DK et al.	2007	HIV	Process/Methods	54 intervention HIV clinics vs. 37 control clinics
Moeschler JB et al.	2009	Pediatric Developmental Delay/Intellectual Disability	Process/Methods	5 clinical genetics practices in Northern New Englan
Newton PJ et al.	2006	Heart Failure	Process/Methods	N/A
Pearson ML et al.	2005	CHF, DM, depression, asthma	Process/Methods	42 organizations in 3 QICs
Rosenman MB et al.	2006	CHF, DM, asthma	Process/Methods	State-sponsored collaborative made up of PCPs of
Ruperto N et al.	2004	Pediatric rheumatology	Process/Methods	2 international networks of pediatric rheumatologists
Schwamm L et al.	2006	Stroke	Process/Methods	N/A
Siegel B et al.	2009	Heart Failure	Process/Methods	2 acute care hospitals in a multi-hospital collaborativ
Sostman HD et al.	2005	Various	Process/Methods	2 academic medical centers
Bray P et al.	2009	Chronic Diseases	Sustainability	13 primary care sites in NC
Brownson CA et al.	2007	Diabetes Mellitus	Sustainability	20 diverse health care teams across the US in a col
Cole SA et al.	2006	Depression & Congestive Heart Failure	Sustainability	24 patients in a Northeast large not-for-profit provide system
Davies E et al.	2005	Various	Sustainability	8 medical groups in MN
Deo S et al.	2009	HIV/AIDS	Sustainability	Cross-section of Ryan White CARE Act funded clini
Desai J et al.	2003	Diabetes Mellitus	Sustainability	Primary care clinics in a large MN managed care or collaborating with the state public health departmen
Fremont AM et al.	2006	HIV	Sustainability	9 VHA clinics
Grant RW et al.	2006	Diabetes	Sustainability	14 primary care practices in a multi-hospital health c
Green CJ et al.	2006	Chronic Disease Management	Sustainability	30 community-based physician participants
Hankinson MT et al.	2006	Urology	Sustainability	5 network facilities of the NJ VHA
Huang ES, et al.	2007	Diabetes Mellitus	Sustainability	17 Midwestern health care clinics in the Health Disp Collaborative
Kilbourne AM et al.	2008	Mood Disorders	Sustainability	Mental health care facility in a VA-academic partner
LaBresh KA et al.	2004	Coronary Artery Disease	Sustainability	24 MA hospitals
Meyer B et al.	2002	Depression	Sustainability	Psychology clinics at Louisiana State University
Nease DE Jr. et al.	2008	Depression	Sustainability	26 primary care clinics in a collaborative

Table A-2. Critical Appraisal

Study	Topic or Condition	Study Description	Study Design	Participants in Analysis	Source of Assessment
Asch, et al. (2005)	Congestive Heart Failure	Study of 4 sites involved with BTS collaborative for chronic heart failure	Observational; comparison cross-sectional study	4 IHI BTS organizations, with 4 controls	Medical records of patients at both intervention and control centers.
Baker, et al. (2005)	Heart Failure	Study of 6 organizations participating in BTS quality improvement collaborative	Observational; comparison cross-sectional study	Patients at participating centers, n = 781	Telephone interviews of patients
Benedetti, et al. (2004)	Diabetes Mellitus	Discussion and Results from a site participating in the Washington State Diabetes Collaborative	Observational; cross-sectional study	Patients at a participating center.	Medical records
Chin, et al. (2004)	Diabetes Mellitus	Evaluation of 19-member Diabetes Health Disparities Collaborative	Observational; Before-and-after study	Patients at participating centers (n= 969); QIC participants via surveys and interviews (n=79).	Medical records; surveys; qualitative interviews
Chin, et al. (2007)	Diabetes Mellitus	Evaluation of effectiveness of a Health Disparities Collaborative	Before-after comparison of participating centers with embedded **randomized** component	Patients at participating centers in 1998, 2000, and 2002 (n = 2364, 2417, and 2212, respectively)	Medical records
Fox, et al. (2006)	Acute MI or Heart failure	Associations between collaborative participation and improved quality of care	Cross-sectional study, (18 months)	Clinics participating in QIC (n = 5).	Self-report of compliance with pre-determined guidelines.
Homer, et al. (2005)	Childhood asthma	Analyzing the effect of practice-level interventions on Pediatric asthma care.	**Clustered randomized controlled trial**	Clinics in greater Detroit and Greater Boston areas (n = 43)	Interviews of parents, via telephone.
Landon, et al. (2007)	General Medical Care	Evaluation of 138 Health Disparities Collaborative participants	Case-control design, with matched internal and external controls	Community Health Centers	Randomly selected patient records.
Landon, et al. (2004)	Patients with HIV infection	Study of 62 of eligible 171 sites participating in CARE Act collaborative	Case-control design, using intervention sites and matched controls	Different types of medical centers delivering HIV care (n=62 intervention sites).	Self-report of participating clinics

Mangione-Smith, et al. (2005)	Childhood asthma	Sites participating in a BTS collaborative for pediatric asthma care.	Quasi-experimental before-and-after design.	Patients at participating and selected control centers	Medical records
Schonlau, et al. (2005)	Childhood asthma	Sites participating in BTS collaborative for asthma care.	Quasi-experimental before-and-after design	Patients at participating and selected control centers	Medical records and surveys of patients.
Philbin, et al. (2000)	Heart Failure	Study of 10 hospitals in upstate New York	**Randomized practice-intervention study; 6 months**	Patients at participating and selected control centers	Medical records and telephone interviews
Siomos, et al. (2005)	Diabetes Mellitus	State Health Plans, participating in a Wisconsin Collaborative Project	Observational; Cross-sectional analysis of medical records	Patients at participating plans	Medical records

Table A-2. Critical Appraisal, cont.

Study	Outcomes	Methodological Status	Duration of Follow-Up	Findings	Internal Validity	External Validity	Clinically Significant Outcomes
Asch, et al. (2005)	23 quality indicators developed for CHF	Baseline measurements (presented). Control sites (yes - minimal discussion of where control sites came from). Standardized outcomes across different sites. Protection from bias (selection issues most prominent). Protection from secular changes (NS).	12 months	(+) effects of counseling, education interventions	Fair	Fair	No
Baker, et al. (2005)	Multiple patient-centered outcomes, including symptom control, self-management, counseling.	Baseline measurements (done). Control sites (yes). Characterization of selected sites (done). Standardization of outcomes (NS). Protection from bias (retrospective, interview-based measures	12 months	(+) Effects of HF QIC	Fair	Fair	**Yes,** some significant.

Benedetti, et al. (2004)	12 clinical outcomes for diabetes care	Baseline measurements (NS). Control sites (none - study involves only a discussion of 1 site). Standardization of outcomes (none). Protection from bias (none mentioned). Protection from secular changes (NS).	Unclear	(+) Effects of collaborative on outcomes	Poor	Poor	No.
Chin, et al. (2004)	Intermediate outcomes related to Diabetes mellitus care	Baseline Measurements (done). Control sites (NS). Characterization of selected sites (done). Standardization of outcomes (done). Protection from bias (NS). Protection from secular changes (NS).	12 months	Inc. rates of HbA1c, podiatry/eye referrals, and lipid assessments.	Fair	Fair	No
Chin, et al. (2007)	Numerous process-of-care and clinical outcomes measures.	Baseline measurements (done). Control sites (no control group for primary before-after analysis). Characterization of selected sites (limited data). Standardization of outcome measures (done). Protection from bias (RCT - yes, CS - no). Secular trends (discussed, not controlled for).	36 months	(+) effects on a number of processes and outcomes of care.	Fair	Fair	No
Fox, et al. (2006)	HF compliance, and AMI composite performance scores	Baseline measurements (unclear - only two measures presented). Control sites (state centers used as controls). Characterization of selected cites (NS). Standardization of outcome measures (done). Protection from bias (limited - composite HF and AMI scores not defined, nor are complete data available). Secular trends (NS).	24 months	(+) Effects on ACEI prescribing patterns and HF/AMI outcomes.	Poor	Poor	No
Homer, et al. (2005)	Primary and secondary asthma-related outcomes	Baseline measurements (given, some detail). Control sites (some differences). Characterization of selected sites (done). Standardization of outcomes measures (done). Protection from bias (randomization).	36 months	No effect of intervention on pre-determined outcomes.	Fair	Fair	**Yes,** not significant

Landon, et al. (2007)	Relevant Quality-of-care measures for Diabetes, Asthma, Hypertension	Baseline Measurements (given). Control sites (yes, internal and external controls). Characterization of selected sites (done). Standardization of outcomes measures (yes). Protection from bias (some sampling, measurement biases present). Secular trends (discussed, unknown influence).	Variable*	(+) Effects on prevention/screening processes of care. No effect on clinical outcomes.	Fair	Good	**Yes,** not significant
Landon, et al. (2004)	HIV-related process of care outcomes	Baseline measurements (small differences). Control sites (described). Characteristics of selected sites (given). Blinded assessment (NS). Randomization (no). Protection from bias (statistical analytic techniques used minimize bias).	18 months	No significant effects on quality of care	Good	Good	No
Mangione-Smith, et al. (2005)	Process-of-care and QOL outcomes	Baseline measurements (some differences). Control sites (selected by reputational process). Blinded assessment (No). Randomization (no). Protection from bias (measurement bias likely, esp. given non-blinded assessment.	12 months	(+) Effects on selected processes of care	Fair	Poor	**Yes**, not significant
Schonlau, et al. (2005)	11 Quality indicators and 4 processes-of-care measurements.	Baseline measurements (none) Blinded assessment (yes). Characteristics of selected sites (info given for patients, but not for sites themselves). Randomization (no). Protection from bias (potential for selection bias based on site selection, also unknown confounders). Secular trends (briefly discussed, no before-after data available).	13 months	(+) Effects on some quality indicators and processes of care	Poor	Poor	**Yes**, not significant

Philbin, et al. (2000)	Process-of-care and clinical outcomes	Baseline measurements (small differences). Blinded assessment (no). Characteristics of selected sites (given). Protection from bias (randomization). Secular trends (NS).	18 months	No effect on most clinical outcomes. Non-significant reduction in hospital length-of-stay in intervention group	Good	Fair	**Yes**, not significant
Siomos, et al. (2005)	6 HEDIS quality of care measures for DM	Baseline measurements (NS). Control sites (none). Blinded assessment (none). Randomization (no). Protection from bias (NS; high potential for selection bias; baseline measurements not presented). Secular trends (not discussed).	36 months†	No statistically significant effect on HEDIS diabetes care measures.	Poor	Poor	No.

* Exact time of site enrollment not available.

† Composition of enrolled sites varied with year of study

Appendix 3: Further Methods

Web-Based Survey

We developed a web-based survey designed using Qualtrics Survey Software to validate themes and concepts uncovered in the in-depth interviews and identify new ones by increasing the representative nature of our analysis and the potential for quantitative data analysis by efficiently reaching larger numbers of informed respondents. Surveying all relevant ICN participants, i.e. the entire ICN member population, allowed maximum power of our results.

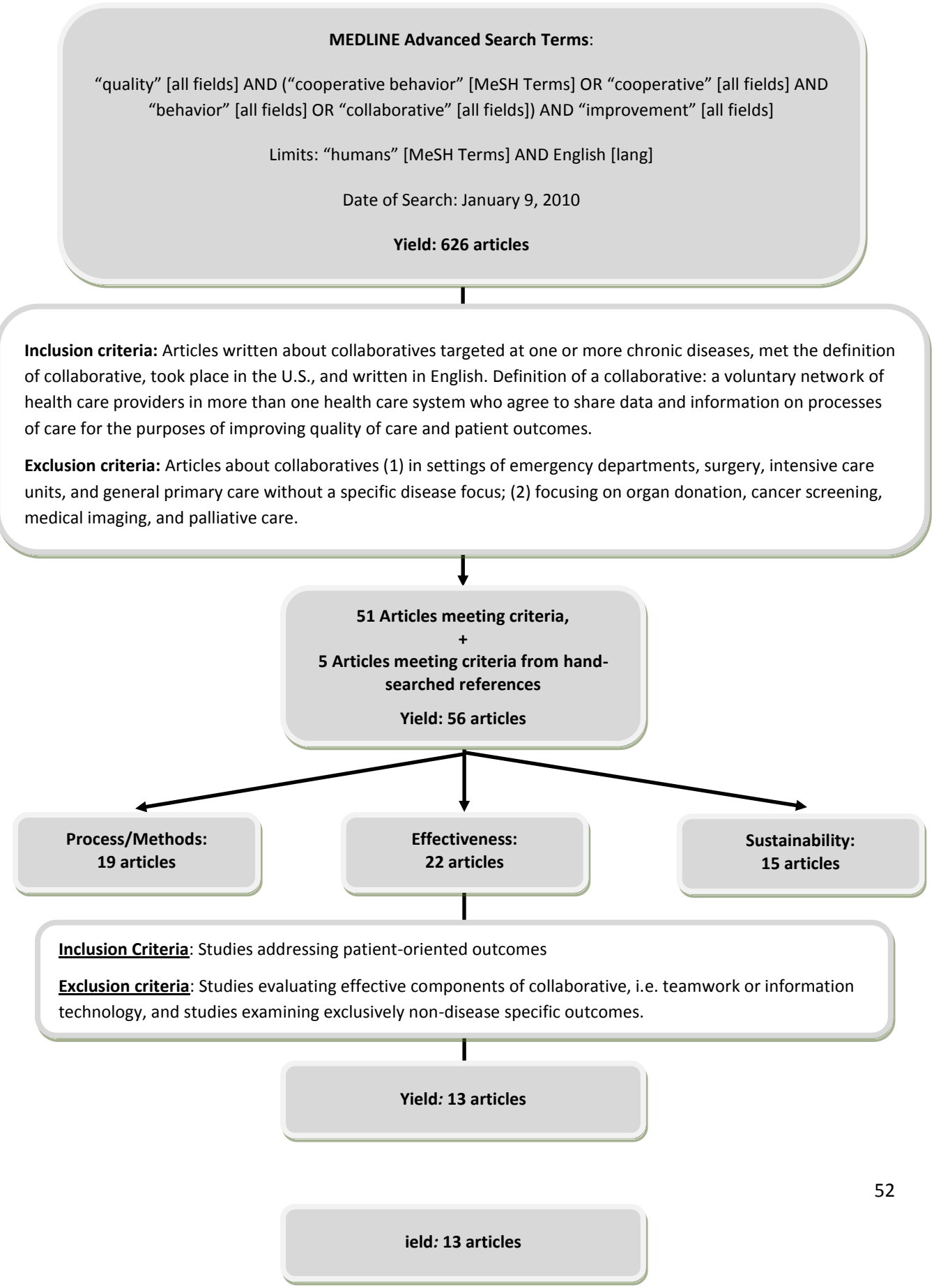
To capture the entire but limited universe of ICN participants, we asked experts in survey methodology and those with expertise in gastroenterology to review our survey rather than conduct a pilot. Expert reviewers included Anthony Viera (family physician and survey expert) and Greg Randolf (quality improvement expert in clinical settings). We provided the reviewers with a brief introduction of our study and the goals of the survey with an emphasis that to pilot the user groups would sacrifice our universe of participants, and asked them for critical feedback to improve the survey. Once we incorporated experts' feedback, we asked two ICN members, Sandra Kim, MD, from University of North Carolina-Chapel Hill, and Amy Donegan, NP, from Nationwide Children's Hospital in Columbus, OH, to evaluate the survey for clarity of questions and response options and ease of completion. We released the final survey to the ICN universe on June 2, 2010, and sent reminders to non-responders weekly for two weeks after the survey release. The final survey is presented in Appendix 6

We uploaded survey results from Qualtrics to an Excel spreadsheet to tabulate descriptive statistics. Response rate was calculated. We quantified themes and concepts addressed by the survey and compared them to those uncovered in the qualitative interviews.

Observation of Participants at an ICN Learning Session

We observed collaborative members at one of ICN's biannual learning sessions in Chicago, IL on April 9-11, 2010. The three-day session included an introductory day-long session for new centers joining the collaborative and two days of learning and research activities for all ICN members. We observed and recorded notes of participant activities as well as their interactions.

Figure A-3: Search Approach for Chronic Disease Collaborative Literature



Appendix 4: Interview Protocol for Existing Sites

ImproveCareNow (ICN) Pediatric IBD Collaborative: Investigation into the Causes of Outcomes Improvement

Fact Sheet/Interview Protocol/Script for in-depth interviews with key informants at 6 to 10 participating institutions.

[Introductory script, embedding study information and agreement to participate:]

Hello, I am [Erica Peterson/Thomas Runge]. Thank you so much for talking with me today. As you recall, I am one of the two research assistants working with Dr. Michael Kappelman and Dr. Sue Tolleson-Rinehart at the University of North Carolina to help evaluate improvement processes in the ImproveCareNow Collaborative.

I am a medical student who is also earning the Master of Public Health degree at UNC. Drs. Kappelman and Tolleson-Rinehart hope that this study of improvement processes at ICN will also become the subject of my master's paper, and my fellow student's master's paper.

We are interviewing collaborative members. As we mentioned in our initial e-mail message, this interview contains several open-ended questions, and should last around 30 minutes, depending on the time you have to give and what you want to tell me. We ask your permission to record the interview in order to assure we capture all you have to say as accurately as possible. We will be furnishing you with a transcript of your interview, and will welcome any additional information you want to add to that.

The intent of this study is to help the ICN Collaborative measure and understand what its improvement processes are accomplishing. We do intend to use the data to complete two master's papers, and we will try to publish those papers in the literature. We will, of course, be making all findings available to the ICN Collaborative for its use. You and your institution will be anonymous, but we do wish to use direct quotes from your interview.

The ICN Collaborative Research Committee agrees to support the project, and the UNC IRB has determined that we are exempt. (IRB exemption # 09-2172). Please don't hesitate to ask any questions about the project – you may contact Dr. Kappelman at Michael_Kappelman@med.unc.edu or Dr. Tolleson-Rinehart at suetr@unc.edu.

Before we continue, would you please give me a verbal agree to the statements I'm about to read?

☐ I AGREE to having this interview tape recorded with a digital voice recorder.

☐ I GIVE PERMISSION for the use of direct quotes from this interview for purposes of analysis.

Now we are ready to begin!

1. First, we wanted to ask you your general impression of collaboratives, and what do you think motivates institutions to participate in them?

2. And thinking about ICN particularly, what about participating in it has been most valuable to you as a health care provider who cares for children with IBD.

3. Now we would like to focus on specific ICN quality improvement activities.

   3.a. First, just off the top of your head, can you give me a list of all the activities the ICN has started?

   [If respondent does not understand, say "That is, just whatever comes to mind when you think of the initiatives or practice changes you are involved in because of ICN."]

   3.b. And which of those things do you think have gone well?

   3.c. And which of those things do you think have not been so successful?

4. The next questions focus on the things **YOU and YOUR INSTITUTION** have done as a result of your participation in ICN. Could you start by listing the changes that have been made at your institution as a result of the collaborative.

5. To respect your time, we want to focus on what you think have been the most important things you've mentioned – the ones you think have been most important in driving improvement at your institution.

In each case, we want to know your institution's experience.

   5.a. Which of the list you just gave me is the most important thing?

   [do repeat back]

   5.b. For [first thing,], can you describe it in more detail? That is, tell me about how you put it into place at your institution, and how it went?

   [CHECKPOINTS: if they DO NOT mention these things, go back and ask…]

- And when did that happen?
- How long did it take to get it going?
- What did you expect it would produce?
- And about when did you expect to see results from it?
- And where does it stand now? Is it successful and ongoing? Still being implemented? Did it stop?

6. **[second thing]**

7. **[third thing]**

8. **[fourth thing]**

Okay, thank you so much! We are nearly done.

Clearly, your commitment to the collaborative is strong – you have invested time and energy in it. Thanks for telling me about your clinic. We also know from the data that outcomes appeared to have improved. With that understood, we want to ask you to step back and think about how improvement happens in two last questions.

9. First, do you think the outcomes improvement is a result of collaborative activity? [Pause] That is, do you think that the collaborative is already paying dividends, or that it is still too soon to have seen the effects on patient outcomes, or somewhere in between?

10. Thank you for telling me about your clinic. Last, I'd like to ask you are there other changes that have occurred at your institution/center that may have affected outcomes (as measured by the collaborative database)?

[Can you think of other changes that would have produced these results, such as changes in your center's provider and/or payor mix, leadership, etc.]

Thank you! That ends the interview. We will be sending you a transcript soon! Is there anything else you would like to tell us?

Appendix 5: Interview Protocol for New Sites

ImproveCareNow (ICN) Pediatric IBD Collaborative: Investigation into the Causes of Outcomes Improvement

Fact Sheet/Interview Protocol/Script for in-depth interviews with key informants at 2 to 3 new institutions.

[Introductory script, embedding study information and agreement to participate:]

Hello, I am [Erica Peterson/Thomas Runge]. Thank you so much for talking with me today. As you recall, I am one of the two research assistants working with Dr. Michael Kappelman and Dr. Sue Tolleson-Rinehart at the University of North Carolina to help evaluate improvement processes in the ImproveCareNow Collaborative.

I am a medical student who is also earning the Master of Public Health degree at UNC. Drs. Kappelman and Tolleson-Rinehart hope that this study of improvement processes at ICN will also become the subject of my master's paper, and my fellow student's master's paper.

We are interviewing collaborative members. As we mentioned in our initial e-mail message, this interview contains several open-ended questions, and should last around 30 minutes, depending on the time you have to give and what you want to tell me. We ask your permission to record the interview in order to assure we capture all you have to say as accurately as possible. We will be furnishing you with a transcript of your interview, and will welcome any additional information you want to add to that.

The intent of this study is to help the ICN Collaborative measure and understand what its improvement processes are accomplishing. We do intend to use the data to complete two master's papers, and we will try to publish those papers in the literature. We will, of course, be making all findings available to the ICN Collaborative for its use. You and your institution will be anonymous, but we do wish to use direct quotes from your interview.

The ICN Collaborative Research Committee agrees to support the project, and the UNC IRB has determined that we are exempt. (IRB exemption # 09-2172). Please don't hesitate to ask any questions about the project – you may contact Dr. Kappelman at Michael_Kappelman@med.unc.edu or Dr. Tolleson-Rinehart at suetr@unc.edu.

Before we continue, would you please give me a verbal agree to the statements I'm about to read?

☐ I AGREE to having this interview tape recorded with a digital voice recorder.

☐ I GIVE PERMISSION for the use of direct quotes from this interview for purposes of analysis.

Now we are ready to begin!

1. First, we wanted to ask you your general impression of collaboratives? What do you think motivates institutions in general to participate in them?

    1.a. And what made you and your institution interested in participating in these kinds of activities?

2. And thinking about your joining ICN particularly, what do you expect will be most valuable to you as a health care provider who cares for children with IBD?

[That is, what improvements do you hope to see through your participation in ICN?]

3. Now, we would like to focus specifically on quality improvement activities.

    3.a. Are there any particular activities you have already started at your clinic to improve the quality of care for your patients?

    [If yes,]
    3.b. And which of those things do you think have gone well?

    3.c. And which of those things do you think have not been so successful?

4. What are the challenges/obstacles you face in implementing quality improvement activities?

Okay, thank you so much! We are nearly done:

In our final question, we want to ask you to step back and think about how quality improvement happens. As you may know, ICN collects various data, including certain patient outcomes.

5. What factors do you think are important for measuring outcomes improvement?

Thanks for telling me about your clinic and your expectations in participating in ICN. That ends the interview. We will be sending you a transcript soon! Is there anything else you would like to tell us?

Appendix 6: Web-Based Survey

1. We can determine when all sites joined ICN, but we are interested in when YOU think YOUR site became fully engaged in ICN and its activities. Please estimate the year you think your center became fully engaged.

a) 2007
b) 2008
c) 2009
d) 2010
e) Our center is not yet fully engaged

2. What types of health professionals are involved with IBD patients in your pediatric IBD program (not necessarily as a part of ICN)? Select all that apply.

a) Physicians
b) Mid-level providers (PAs, NPs, etc.)
c) Nurses
d) Clinical pharmacists who are assigned to the program
e) Nurses assistants or medical assistants
f) Nutritionists, dietitians
g) Psychologists or psychiatrists
h) Social workers
i) Financial counselor
j) Other: Please specify _____

3. What best describes you? If you have more than one role, please choose the one that is most applicable right now, to the pediatric IBD program at your center.

a) I am a physician who cares for patients with IBD
b) I am a mid-level provider (NP, PA)
c) I am a pharmacist
d) I am a nurse
e) I am a dietitian
f) I am a research assistant
g) I am a quality improvement specialist
h) Other: Please specify _____

3a. Please estimate what fraction of your total IBD patient population is actively followed in the ICN database (e.g. most visits for these patients are entered)

a) Less than 20%
b) Between 20% and 40%
c) Between 40% and 60%
d) Between 60% and 80%
e) More than 80%
f) Unable to estimate

4. The statements below are a list of things people have told us about why the ICN collaborative is important to them. Please use the slider bars (0-10) below to tell us how important or unimportant each of these things is to YOU and YOUR involvement in ICN. If something does not matter to you AT ALL, please drag the slider bar to zero.

a) Using quality improvement strategies to help patients

0 1 2 3 4 5 6 7 8 9 10

b) Helping health care providers learn leadership skills

0 1 2 3 4 5 6 7 8 9 10

c) Working together and sharing with providers at other centers

0 1 2 3 4 5 6 7 8 9 10

d) An opportunity for research

0 1 2 3 4 5 6 7 8 9 10

e) Developing, agreeing to, and using best practice standards

0 1 2 3 4 5 6 7 8 9 10

f) Other - Please specify.

0 1 2 3 4 5 6 7 8 9 10

5. As a health care provider, what has been (or what do you expect to be) the SINGLE most valuable aspect of being a member in ImproveCareNow?

a) Using quality improvement strategies to help patients
b) Helping health care providers learn leadership skills
c) Working together and sharing with providers at other centers
d) An opportunity to do research
e) Developing, agreeing to, and using best practice standards
f) Other: Please specify _____

6. If you have used any of the following activities, please move the slider bars below to rate each of the following according to HOW VALUABLE THEY ARE to improving the care of IBD patients at your center.
If things are NOT VALUABLE at all, please move the slider bar to zero, to make sure your choice registers.
If you have NEVER DONE an activity, check the box "Not Applicable."
In the "other" option, if you have no additional comments, please select "Not applicable."

a) Standardized IBD Clinic Template

0 1 2 3 4 5 6 7 8 9 10

b) Model Care Guidelines

0 1 2 3 4 5 6 7 8 9 10

c) Nutrition/Growth Algorithms

0 1 2 3 4 5 6 7 8 9 10

d) Dedicated IBD Clinic

0 1 2 3 4 5 6 7 8 9 10

e) Monthly Narrative Reports submitted to ICN

0 1 2 3 4 5 6 7 8 9 10

f) Running small tests of change (PDSAs) at your site

0 1 2 3 4 5 6 7 8 9 10

g) Pre-visit planning

0 1 2 3 4 5 6 7 8 9 10

h) Regular meetings to discuss patients from Population Management Reports (PMR)

0 1 2 3 4 5 6 7 8 9 10

i) Multidisciplinary team meetings, other than those used to discuss PMR

0 1 2 3 4 5 6 7 8 9 10

j) Real-time process auditing

0 1 2 3 4 5 6 7 8 9 10

k) Patient self-management support (e.g. education sessions, support groups, materials)

0 1 2 3 4 5 6 7 8 9 10

l) Other – Please specify

0 1 2 3 4 5 6 7 8 9 10

7. ICN provides several services and educational opportunities to its sites. Now we'd like you to rate the value of each of the following. IF YOU HAVE USED any of the following activities, please MOVE the slider bars below to rate each according to HOW VALUABLE THEY ARE to improving the care of IBD patients at your center.
If things are not valuable at all, please move the slider bar to zero, to be sure your choice registers.
If you HAVE NEVER USED an activity, check the box "Not Applicable."
In the "Other" option, if you have no additional comments, please select "Not applicable."

a) Conference calls and webinars

0 1 2 3 4 5 6 7 8 9 10

b) Email/Listserv

0 1 2 3 4 5 6 7 8 9 10

c) Extranet

0 1 2 3 4 5 6 7 8 9 10

d) Monthly data reporting from ICN

0 1 2 3 4 5 6 7 8 9 10

e) Population management reports

0 1 2 3 4 5 6 7 8 9 10

f) Semi-annual Learning Sessions

0 1 2 3 4 5 6 7 8 9 10

g) Other – please describe.

0 1 2 3 4 5 6 7 8 9 10

8. Below are some potential obstacles to participation in ICN. Please use the slider bars to indicate how challenging these factors are, at your center. If one or more of these is NOT a challenge for your site, please move the slider bar to zero.
If you don't know or cannot assess, please check the box "Not Applicable."
In the "Other" option, if you have no additional comments, please select "Not Applicable."

a) Financial Costs

0 1 2 3 4 5 6 7 8 9 10

b) It takes my time

0 1 2 3 4 5 6 7 8 9 10

c) It takes the time of other staff

0 1 2 3 4 5 6 7 8 9 10

d) It takes time to see change

0 1 2 3 4 5 6 7 8 9 10

e) Clinic restructuring

0 1 2 3 4 5 6 7 8 9 10

f) Transition to electronic medical records (EMR), or other changes to medical record

0 1 2 3 4 5 6 7 8 9 10

g) Turnover of specific, key personnel

0 1 2 3 4 5 6 7 8 9 10

h) Lack of leadership commitment to ICN, or QI in general.

0 1 2 3 4 5 6 7 8 9 10

i) Difficulty changing the practices of physicians, nurses, and staff

0 1 2 3 4 5 6 7 8 9 10

j) Other – Please specify.

0 1 2 3 4 5 6 7 8 9 10

9. Finally, please address the relative effect of each of the variables below on improved patient outcomes in ICN, since 2007. Please MOVE the slider bars below to rate each of the following according to HOW IMPORTANT THEY ARE to improving patient outcomes.
If things are NOT IMPORTANT at all, please MOVE the slider bar to zero, to be sure your choice registers.
If you don't know or cannot assess, please check the box "Not Applicable."
In the "OTHER" column, if you have no additional comments, please select "Not Applicable."

a) Improved medication management, as a result of scientific or therapeutic advances.

0 1 2 3 4 5 6 7 8 9 10

b) Continuing education about IBD, independent of ICN

0 1 2 3 4 5 6 7 8 9 10

c) Other secular trends, that is, changes in medicine generally that affect all practices

0 1 2 3 4 5 6 7 8 9 10

d) Natural stabilization of the course of disease over time, occurring idnependent of ICN

0 1 2 3 4 5 6 7 8 9 10

e) Other changes in your practice (addition or loss of key physicians, nurses, or other staff)

0 1 2 3 4 5 6 7 8 9 10

f) New patient-parent support mechanisms unrelated to ICN

0 1 2 3 4 5 6 7 8 9 10

g) Variation in scoring of the PGA (Physician Global Assessment)

0 1 2 3 4 5 6 7 8 9 10

h) How patients were entered into the database (i.e., early on, sicker patients more likely to be entered due to frequency of clinic visits compared to healthier patients)

0 1 2 3 4 5 6 7 8 9 10

i) The ImproveCareNow collaborartive intervention

0 1 2 3 4 5 6 7 8 9 10

j) Other – Please specify.

0 1 2 3 4 5 6 7 8 9 10

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